T.J. Samson
Your Community. Your Hospital.

Bud Wethington
President and Chief Executive Officer

1301 North Race Street • Glasgow, KY 42141 • P 270.651.4157

June 29, 2015

Tricia Orme
Office of Legal Services
275 East Main Street 5 WB
Frankfort, Kentucky 40601

Dear Ms. Orme:

T.J. Samson is an independent 196 bed not-for-profit hospital and multispecialty physician practice that provides services to people in over 12 counties in Kentucky and approximately 1,000 patients per day. Our organization has been providing health services and wellness education to patients since 1929. We are surrounded by eight small rural hospitals, several of which are critical access, and all of which are struggling financially from reduction in reimbursement, reduced census and reduced overall utilization. Given all the changes in health care, our industry continues to see increased expenses due to the regulatory requirements, technology investments and increasing salaries.

I have worked in other states that have stripped their CON programs bare or eliminated them completely, and I have firsthand experience about how quality, cost and utilization are negatively impacted. Having a radiation center on every corner does not improve access to care or improve quality.

I fully support the preservation of the Certificate of Need Program and encourage the cabinet to make the program even more robust to ensure that it upholds the statutory intent of the Kentucky CON program "safe, adequate and efficient medical care; that the proliferation of unnecessary health-care facilities, services and equipment; and that such proliferation increases the costly duplication and underuse of such facilities and services and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth."

I fully support the process of modernizing the CON process to include quality thresholds, technology requirements and provisions to create a continuum of care. It is vital that the Cabinet develop and review modeling and analysis to understand how the proposed revisions will actually impact existing and potential new providers in all regions of Kentucky. I urge you to fully analyze all the proposed changes and involve health care providers in the state to gain insight on the impact of changes prior to implementation. Some of the proposed changes may provide significant hardship to existing

providers, ultimately reducing access to health care in the long term for rural areas of the Commonwealth.

The elimination of the angioplasty pilot program dramatically reduces access to quality medical care to the residents of rural regions. T.J. Samson began offering this service in 2005 and this program has saved hundreds of lives. We have delivered the service safely and cost effectively and believe that other hospitals in the rural areas can replicate our outcomes if they are given the opportunity to develop the necessary talent, policies and infrastructure.

At T.J. Samson we are constantly working to improve the service and care that we provide to our patients. I support the utilization of quality metrics when they are appropriately linked and the accuracy is documented. The Cabinet needs to remember that many factors will impact the quality metrics such as the high rate of poverty in a region. It is a necessity to recognize that an organization must progressively track their quality metrics and continually follow action plans to address their gaps in delivery. An organization plans for improvement should be considered when reviewing a Certificate of Need application.

Special Care Neonatal Beds

I concur with the KHA recommendation to have on-site physician coverage (neonatologist) for Level III beds within 30 minutes to be consistent with federal EMTALA regulations, CMS Conditions of Participation and most hospital medical staff bylaws including those at T.J. Samson.

Long Term Care

T.J. Samson supports the proposed solution presented by KHA that would allow hospitals with underutilized acute beds to convert the beds to long term care beds. This recommendation would require that a facilities' acute care beds have an occupancy rate of less than 70%, only convert licensed acute beds and be limited to operate the converted beds at their existing location.

Home Health Agency

Home Health services may be one of the most valuable tools for hospitals to utilize to help improve their patients' health outcomes. Therefore, we support allowing hospitals to expand to offer home health services. T.J. Samson supports the utilization of quality metrics, but a hospital's readmission rate does not necessarily correlate with its ability to offer quality Home Health services.

Cardiac Catheterization

T.J. Samson strongly encourages the Cabinet to withdraw the proposal to eliminate the pilot angioplasty program from the State Health Plan. We have been afforded the opportunity to offer this service in our rural community for the past ten years and hundreds of patients have survived a heart attack because of this service being offered in their community.

Magnetic Resonance Imaging Equipment

I support maintaining the CON need criteria for establishing Magnetic Resonance Imaging Equipment and strengthening the requirement to mandate accreditation from the American College of Radiology by all applicants. This requirement would establish a minimum magnet quality as well as a mandates experience level for all staff and physicians.

Megavolt Radiation Equipment

Megavolt Radiation is a very complex and costly service to provide. It is important that this service is provided within a reasonable driving distance and this can be done by utilizing a defined planning area and maintaining a population need based criteria. It is my understanding that some areas are in need of this service; however, CONs have been issued for the service in their region but not implemented. This issue must be addressed by the Cabinet.

Ambulatory Surgery Center

There is currently ample capacity in Kentucky for ambulatory surgery. A simple survey of all surgery providers by KHA in 2014 indicated that 89% of all providers have a lead time of less than two weeks for elective outpatient surgery and only 2% indicated their wait exceeds a month. Providers are able to flex their hours of operation and staff to meet the demand. In states where the CON requirements for Ambulatory Surgery Centers were eliminated there has been a gross proliferation of services that does not improve access to care due to the documented incidents of cherry-picking.

Outpatient Health Center

A provision needs to be developed to allow a hospital to seamlessly convert to an outpatient health center if for some reason they cannot continue to operate as a full service hospital. Not every community in Kentucky can support an acute care hospital or a critical access hospital. Eliminating the review criteria for an outpatient health center would not allow a community to benefit from a redefined care delivery model.

While the Certificate of Need program is vital to the citizens of Kentucky, the economy of Kentucky is dependent on strong health care providers with business operations in Kentucky. The benefits of increasing providers, but decreasing volumes, will not only have a negative effect on quality of care; it will also negatively impact the economy.

Sincerely,

Bud Wethington
President and CEO
T.J. Regional Health

Appalachian Regional Healthcare, Inc.
www.arh.org

June 30, 2015

Ms. Tricia Orme
Office of Legal Services
275 East Main Street 5 WB
Frankfort, KY 40601

Dear Ms. Orme:

Appalachian Regional Healthcare, Inc. strongly supports maintaining a Certificate of Need program that provides access to quality health services across the Commonwealth of Kentucky. I am a member of the KHA Certificate of Need Committee and I support the KHA position on the State Health Plan. I would like to address several significant areas of concern for ARH.

As the largest rural healthcare provider in Eastern Kentucky, we face significant challenges which were appropriately detailed in State Auditor Adam Edelen's report. Our region of the Commonwealth continues to have substantial economic challenges and the health statistics of the region are some of the worst in the nation. We have provided care for this region for over 60 years and we work diligently to provide and expand services so that our patients do not have to travel great distances to receive quality healthcare services. Loosening the criteria for ambulatory surgery will have a very negative effect on our ability to continue to operate many services. Surgery is one of the few profitable service lines that we operate. It allows us to provide other much needed services such as obstetrics, emergency department and many wellness outreach initiatives. Our hospitals have plenty of capacity to meet the surgical needs of our patients. In addition, the proposed quality metrics for readmissions and mortality rates are not truly related to outpatient surgical services. If the Cabinet wanted to look at quality data for surgery, a better quality metric would be the Surgical Care Improvement Project Core Measure set. The proliferation of ASCs will do absolutely nothing to improve the quality of healthcare services and will only duplicate very costly services. ARH supports maintaining the existing ASC criteria in the current state health plan.

ARH's home health operations are a core service line. Hospital readmission rates should not be used as criteria to expand home health. Readmission rates are not adjusted for the socio-economic factors that greatly impact patient outcomes. Our patients often go home to places without running water, and appropriate heat and air conditioning. Patients also lack the resources to purchase healthy foods and many needed pharmaceuticals. These conditions do not facilitate a patient staying well and adhering to a healthy lifestyle. Also, critical access hospitals are not included in the readmission and mortality reporting requirement therefore they have no data. The proposed changes would exclude CAHs from expanding into home health. We do not support the exemption for Accountable Care Organizations to

expand home health. Merely being an ACO has no relevance on the ability to provide quality home health services.

Healthcare is a core business in Eastern Kentucky. ARH is the largest private employer in the region and providing good paying jobs and benefits is core to our mission. We are very concerned that changes to the state health plan will jeopardize our ability to provide much needed services in our rural region and further endanger the economic situation.

Sincerely,

Hollie Harris Phillips

Hollie Harris Phillips
Vice President Corporate Strategy

PINNACLE TREATMENT CENTERS
1317 Route 73 North, Suite 200 • Mt. Laurel, NJ 08054

June 30, 2015

VIA FAX ONLY (502) 564-7573

Ms. Tricia Orme, Administrative Specialist III
Cabinet for Health and Family Services
Office of Legal Services
275 East Main Street, 5W-B
Frankfort, Kentucky 40621

RE: 900 KAR 5:020. State Health Plan for facilities and services.

Dear Ms. Orme:

Thank you for the opportunity to comment on proposed revisions to the State Health Plan ("SHP"). Please accept these comments on behalf of Pinnacle Treatment Centers KY-I, LLC ("Pinnacle") and the facilities it operates throughout Kentucky in opposition to the proposal to remove the Chemical Dependency Treatment Beds Review Criteria from the SHP. Among the continuum of care services offered in Kentucky, Pinnacle provides care in a licensed chemical dependency treatment facility located in Georgetown, Kentucky.

KRS 216B.010 delineates the findings and purposes of the CON law:

> Insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care; that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and under use of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth.

With the expansion of behavioral health services in Kentucky to combat the increasing alcohol and substance abuse problems the state is experiencing, it seems that the relaxing of standards to approve additional chemical dependency treatment beds may be a good idea. Nothing, however, can be further from the truth. By significantly relaxing the CON requirements for chemical dependency treatment beds, there could be a proliferation of unnecessary providers seeking to establish these beds, which could result in the same problem the Commonwealth experienced with suboxone clinics. When the issue with suboxone clinics arose, both the Kentucky Board of Medical Licensure and the Department for Medicaid Services promulgated regulations to address the abuses.

Often, individuals presenting for treatment have dual diagnoses and require care by qualified individuals. Currently, most of the chemical dependency treatment beds are owned and operated by acute care hospitals. Pinnacle is one of the exceptions. The undersigned has

RE: 900 KAR 5:020. State Health Plan for facilities and services.

experience in operating substance use treatment centers in several states and has seen the negative results that can come with relaxed regulation of chemical dependency treatment beds. New Jersey relaxed its rules and is now trying to restrict additional beds because people in dire need of care were inappropriately placed in hotel-type accommodations with no structured treatment program. Likewise, California has no restrictions and no process to determine whether an entity has the appropriate resources and experience to support a quality system that rehabilitates people.

While there are regulations in Kentucky governing chemical dependency treatment services and facility specifications, there is no separate regulation governing the operations and services of a chemical dependency treatment facility. This lack of regulatory framework, coupled with the proposed relaxation of CON requirements for chemical dependency treatment beds, may result in the approval of a plethora of new chemical dependency treatment facilities, causing the proliferation of unnecessary, costly services and the underuse of existing services that have capacity to serve additional patients. Specifically, this may lead to a proliferation of providers that use inexpensive, unsupervised lodging for the residential component of care and the provision of out-of-network intensive outpatient therapy at an ultra-high cost. Under this undesired "Florida Model" of care, patients may unwittingly exhaust their substance abuse benefits or be personally responsible for high private-pay expenses. Such results directly contradict the statutory mandates in KRS 216B.010 and are clearly not in the best interest of the health, safety, and welfare of Kentucky citizens.

Currently, a CON application seeking to establish chemical dependency treatment beds in Kentucky is processed through full, formal review. Under formal review, the applicant has the burden of proof to show that the application is consistent with all five of the statutory criteria: (1) Consistency with plans; (2) Need and accessibility; (3) Interrelationships and linkages; (4) Cost, economic feasibility, and resources availability; and (5) Quality of services. KRS 216B.040(2)(a)2.a. – e. By removing the Chemical Dependency Treatment Beds Review Criteria from the SHP, CON applications seeking to establish such beds would be reviewed under the expedited, non-substantive review process.

Under non-substantive review, a CON application is presumed to be needed, a presumption that must be rebutted by an affected party by clear and convincing evidence. The clear and convincing evidence standard is a much higher standard than that which is required in the formal review process. Further, under non-substantive review, an applicant is not required to demonstrate that it has sufficient interrelationships and linkages with existing resources to provide quality care and that it is a financially viable provider. Without evidence of an applicant's ability to provide services in a cost-effective and quality manner, the health, safety, and welfare of Kentucky citizens could be compromised, particularly when the applicant is not required to prove that it has the experience and qualifications to appropriately treat this patient population.

RE: 900 KAR 5:020. State Health Plan for facilities and services

Merely providing a bed and medicine fails the patient. A patient entering a chemical dependency treatment facility has the right to expect a safe environment in which counseling and medication-assisted treatment, if appropriate, is offered by qualified and experienced providers. The patient has the right to expect access to a continuum of care to assist him/her in achieving sobriety. If the proposed revision to the SHP stands, it will be easier for new providers to enter the market without being required to show their ability to provide appropriate services. It may also allow these new providers to "cherry pick" most of the well-insured patients, which may detrimentally impact existing providers and ultimately reduce their patient volumes. As such, Pinnacle urges the Cabinet to maintain the formal review process for CON applications seeking to establish chemical dependency treatment beds.

Thank you for your consideration of these comments. Please feel free to contact me if you have any additional questions.

Sincerely,

Joseph Pritchard
Chief Executive Officer

Walter E. May
President/CEO

PIKEVILLE MEDICAL CENTER

June 30, 2015

Ms. Tricia Orme
Office of Legal Services
275 East Main Street 5 WB
Frankfort, Kentucky 40601

Via Facsimile: (502) 564-7573

Re: Proposed State Health Plan Changes

Dear Ms. Orme:

I am writing on behalf of Pikeville Medical Center to submit comments on the proposed changes to the State Health Plan. Those comments are as follows:

Cardiac Catheterization
Pikeville Medical Center supports restricting comprehensive and therapeutic cardiac catheterization programs to facilities which also have open-heart surgery programs. Obviously, some cases will require swift surgical intervention for preservation of the patient's life and health. Transfer of patients between facilities can be challenging due to distance and availability of ambulance services and this can be exacerbated in rural areas. Air transport is also not always available due to weather conditions. This can be exacerbated in the mountainous regions of the state due to the prevalence of fog and limited landing sites.

Home Health
Pikeville Medical Center opposes amending the State Health Plan to include an exception to Criteria 1 and 2 for hospitals and existing home health agencies that meet certain benchmarks and for accountable care organizations. The national benchmarks referenced in the proposed amendment do not relate to the need issue addressed in criteria 1 and 2. The national benchmarks referenced for hospitals do not relate to their ability to operate a home health agency. The proposed exception for ACO's does not even contain criteria except that the ACO operate in that county. Inclusion of such exceptions will be counter to the statutorily expressed goals of Kentucky's CON program "to insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care; that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth."

Ambulatory Surgery Centers
Pikeville Medical Center opposes the proposed amendments to the State Health Plan concerning ambulatory surgery centers ("ASCs"). ASCs are notorious for cherry-picking the patients with the best paying insurance plans while leaving the local hospital with those patients who are indigent, uninsured, or underinsured, thus threatening the long-term financial viability of

community hospitals. As such, the Commonwealth should adopt measures to restrict, rather than proliferate the number of ASCs in the state.

Pikeville Medical Center opposes exceptions to population-based need criteria for ASCs. With the proposed removal of the requirement that an ASC have a transfer agreement with a hospital within 20 minutes normal driving time combined with the proposed exceptions to criteria 1 and 2 (the utilization criteria) for ASCs that are majority owned by a hospital creates the real possibility of hospitals establishing ASCs far from their own main campus and near other unaffiliated hospitals which will undoubtedly work to the financial detriment of that other hospital and unnecessary duplication of services. At a time when many of Kentucky's community hospitals are struggling to survive financially and have substantial operating room capacity, there is no reason to introduce duplicative services and further financial hardship.

Further, several of the benchmarks proposed for hospital majority owned ASCs that would allow them to ignore criteria 1 and 2 (such as the readmission rates for heart failure, pneumonia, COPD, and stroke) are not related to the hospital's or the ASC's ability to provide quality surgical services. For example, there is no correlation between a hospital's ability to achieve low readmission rates for pneumonia and its ability to deliver high-quality surgery services in an ASC many miles from its campus.

Pikeville Medical Center also opposes the proposed exception to criteria 1 and 2 for physician-owned ASCs in operation for 10 years. The result will likely be the enhancement of wealth of a few already wealthy individuals to the detriment of hospitals, most of which are non-profit institutions with a long history of charitable services to their communities and with the presumed expansion of services offered by the physician-owned ASC above the services that were offered prior to obtaining a CON, there would again be unnecessary duplication of services given the excess operating room capacity that exists at most community hospitals.

<u>Magnetic Resonance Imaging & Megavoltage Radiation Equipment</u>
For the same reasons expressed above, Pikeville Medical Center opposes the proposal to eliminate need criteria for MRI and the proposed exception to the need criteria for megavolt radiation equipment. The need criteria throughout the State Health Plan is necessary to promote the goals of the CON program to ensure that there is not proliferation of unnecessary health-care services or duplication and underuse of such services.

Sincerely,

Walter E. May

Walter E. May
President & CEO

BAPTIST HEALTH

PHONE: 502.896.5000
2701 Eastpoint Parkway Louisville, KY 40223

June 30, 2015

Ms. Tricia Orme
Office of Legal Services
Cabinet for Health and Family Services
275 East Main Street 5 W-B
Frankfort, KY 40601

Re: Proposed Amendments to the State Health Plan

Dear Ms. Orme:

Baptist Healthcare System, Inc. ("Baptist Health") commends the Cabinet for Health and Family Services for its extensive work related to modernization of the Certificate of Need program. As stated in Baptist Health's letter to the Cabinet dated December 8, 2014 regarding the Cabinet's request for input on the Special Memorandum Certificate of Need Modernization: Core Principles, Baptist Health believes that the Cabinet's goals related to CON Modernization are laudable and Baptist Health supports the core principles outlined by the Special Memorandum. Further, Baptist Health appreciates the opportunity to provide comments both to the Special Memorandum and the draft *2015-2017 State Health Plan* ("SHP").

While Baptist Health generally supports the goals of the Cabinet's draft SHP, there are certain proposed changes that Baptist Health encourages the Cabinet to examine in an effort to determine what is in the best interest of Kentucky residents and their healthcare needs. Notably, Baptist Health opposes the proposed changes to the SHP criteria for Ambulatory Surgery Centers ("ASC"). Specifically, ASCs should remain subject to the CON process to avoid the proliferation of unnecessary services. Further, subjecting ASCs to the CON process protects the surgical volumes at Kentucky hospitals, which rely heavily on surgery volumes in order to finance emergency services and other care to individuals without regard for their ability to pay. In order to provide the Cabinet with a comprehensive view of Baptist Health's response to the proposed amendments to the SHP, please find enclosed an outline of Baptist Health's position on the proposed plan.

Additionally, Baptist Health opposes the proposed changes to the SHP criteria for hospitals seeking to provide Level III neonatal services. While Baptist Health understands that the SHP is not a licensure rule, it applauds the Cabinet's efforts to ensure quality healthcare services are provided to Kentucky residents. However, the proposed requirements are not consistent with national standards of care for neonatal services. In 2012, the American Academy of Pediatrics ("AAP") published a policy statement defining the levels of neonatal care. The AAP states that Level III neonatal facilities should have neonatal personnel, such as

neonatologists, neonatal nurses or respiratory therapists, continuously available. The proposed changes to the SHP criteria go well beyond the national standard set forth by the AAP. Baptist Health encourages the Cabinet to revise this criteria to bring it in line with the AAP's standards.

Thank you for your consideration of Baptist Health's comments. Baptist Health welcomes the opportunity to discuss its comments further.

Sincerely,

Andy Sears
Chief Strategy and Marketing Officer

Baptist Health
Review of Draft 2015 – 2017 State Health Plan

I. Acute Care

a. Acute Care Beds – Technical notes were deleted and planning area for acute care beds was redefined to include only county of residence and Kentucky contiguous counties.
Baptist Health does not oppose

b. Physical Rehab Beds – Added quality criteria and 80% occupancy threshold for adding beds
Baptist Health does not oppose

c. Neonatal Beds
   i. Deleting requirement that applicants for Level 2 and Level 3 neonatal services that already provide Level 4 neonatal services have to have an affiliation agreement with another Level 4 provider.
   Baptist Health does not oppose

   ii. Adds requirement that applicants for Level 3 neonatal services have a neonatologist continuously available 24 hours per day and able to be on-site in 15 minutes. Additionally, when a neonatologist is not on-site, the applicant must have on-site either a neonatal advanced practice registered nurse with training and skills specified in the most recent published edition of the *Guidelines for Perinantal Care*, or a fellow in an approved Neonatal-Perinatal Medicine Fellowship.
   Baptist Health opposes these proposed changes to the Level III neonatal beds criteria.

d. Open Heart – No changes proposed

II. Behavioral Health

a. Behavioral Health – No changes proposed except name change from mental health

b. Psychiatric Residential Facilities – No changes proposed

III. Long Term Care

a. Nursing Facility Beds – Allows one licensed nursing facility to transfer to another licensed facility up to 10 beds per year if occupancy thresholds are met
Baptist Health does not oppose

b. Home Health

i. Allows a hospital to establish a home health agency in the county it is located or a contiguous county if it meets or exceeds National Hospital Compare benchmarks

ii. Allows existing programs to expand into contiguous counties to their service area
Baptist Health supports proposed changes

c. Hospice Services – No changes proposed

d. Residential Hospice Facility – No changes proposed

e. Adult Day Care – Removed from State Health Plan, only need to apply for a license to establish services

f. Intermediate Care for Intellectual Disabilities (IID) – No changes proposed

IV. Diagnostic and Therapeutic Equipment

a. Cardiac Catheterization – No changes for diagnostic catheterizations, but facilities can no longer apply for therapeutic catheterization labs without an open heart program and must be able to document at least an unmet need of 200 additional therapeutic procedures
Baptist Health does not oppose

b. MRI – Removed from the SHP
Baptist Health supports proposed change

c. Megavoltage Radiation

i. Allows a hospital or entity 50% owned by a hospital that is accredited by American College of Surgeons Commission on Cancer as comprehensive community cancer program to establish a radiation therapy program anywhere in the state

ii. Proposes that all existing programs have to be performing at an average of 4000 procedures per therapy unit.

Baptist Health recommends that the proposed language for Megavoltage Radiation be changed such that only a Kentucky licensed hospital could be approved and only in its county of residence or contiguous county. This suggested change follows the definition for the planning area (county of the proposed program and contiguous).

d. Position Emission Tomography – No major changes proposed

e. New Technology – No changes proposed

V. Miscellaneous Services

a. Ambulance Services – Have been removed from State Health Plan

BH supports the proposed change

b. Ambulatory Surgery Centers

i. Major change allows a hospital to establish an ASC if they meet or exceed hospital compare benchmarks

ii. Proposed changes also allow a private physician or physician group, 100% owned by physicians and operated in Kentucky for ten prior years and having performed surgical procedures in their office for 5 years, to establish an ASC in their home county

Baptist Health opposes the proposed changes to the ASC criteria.

c. Chemical Dependency Treatment Beds – Removed from State Health Plan

d. Outpatient Healthcare Center – Removed from State Health Plan

Owensboro Health

June 30, 2015

Tricia Orme
Office of Legal Service
275 E. Main St. 5 W-B
Frankfort, KY 40601

Re: 900 KAR 5:020
2015-2017 State Health Plan

Dear Ms. Orme:

I am writing on behalf of Owensboro Health, Inc. ("OHI") and its affiliated companies to express our comments on the proposed changes in the 2015-2017 Kentucky State Health Plan. OHI operates Owensboro Health Regional Hospital, the largest hospital in Western Kentucky, with 415 acute care beds (including 16 neonatal beds), as well as 20 comprehensive physical rehabilitation beds, 12 psychiatric beds and a 30-bed nursing facility unit. We operate a home health agency serving Daviess, Hancock, McLean and Ohio Counties. OHI and our affiliated entities also operate numerous licensed outpatient facilities, including an ambulatory surgical center and rural health clinic. We are also in the final stages of acquiring Muhlenberg Community Hospital and its related outpatient facilities.

OHI and our facilities have long provided a very high level of quality healthcare services. We are Joint Commission accredited and regularly receive high scores in Hospital Compare, Home Health Compare, Health Grades, Beckers Hospital Review and others We have long supported Kentucky's Certificate of Need program and worked with the Cabinet and its predecessors in the health planning process. We are very concerned that some of the proposed changes will reduce quality of care, harm existing providers, especially rural hospitals, and lead to an unnecessary proliferation of unneeded health facilities and services.

GENERAL COMMENTS

We are concerned that several of the proposals will harm quality of care. As a general rule, we suggest that the Cabinet make no change unless it can be demonstrated that the change will improve quality of care. Along these lines, we ask that the Cabinet proceed very cautiously in moving services or facilities into nonsubstantive review, or in removing them from CON review altogether. On each such proposed move, the Cabinet should specifically address and explain how the proposed move would improve quality of care.

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In a similar vein, while we support the Cabinet in including quality standards in the State Health Plan, many of the proposals rely on benchmarks that are not related to the service or facility being proposed in an application. For example, how do mortality rates for stroke patients relate to a hospital's ability to establish a quality ASC? To the extent that the Cabinet decides to include quality benchmarks, they should be directly related to the services under review.

SPECIFIC SERVICES

I. Ambulatory Surgical Center

We oppose the Cabinet's proposed Ambulatory Surgical Center Review Criteria 5 and 6 at page 60 of the 2015-2107 Kentucky State Health Plan. These criteria create two potentially very broad exceptions to the legislative mandated need methodology for ASCs. This could easily lead to a proliferation of unneeded ASCs and could lower the quality and raise the cost of outpatient surgery services.

Proposed ASC Criterion 5 would make applications by certain hospitals, or entities with >50% ownership by those hospitals, automatically consistent with the SHP. It does not limit the number or location of ASCs to be established. It does not take into account any factors concerning the need for another ASC in the area. On its face, it appears that it would even apply to out-of-state hospitals proposing ASCs in Kentucky.

We have seen no evidence that the Cabinet has done any analysis as to whether additional ASCs are needed in any particular part of the state and, if so, how many are needed. In the absence of such an analysis, and a methodology adopted from that analysis, this provision not only violates the express language of Part I(A)(6) of the State/Executive Branch Budget, but it is also very poor health planning.

Proposed ASC Criterion 6 would make applications by certain physicians or groups automatically consistent with the SHP. Again, this does not appear to be based upon any analysis as to where or how many additional ASCs may be needed. As we have previously pointed out, encouraging physicians to establish ASCs can lead to reduced quality and overcharging as well as shifting higher paying commercial cases to the physician owned centers while leaving the self-pay and lower paying governmental payors at the hospital sites. We have provided evidence on several occasions of extremely high charges to employers by physician-owned ASCs across the river from Kentucky. We are distressed that the Cabinet has apparently misconstrued this as evidence that we should allow them to do the same thing in Kentucky.

There is an abundance of hospitals and ASCs in most parts of Kentucky. If there were a need for additional ASCs in particular locations, the Cabinet should, indeed it must, adopt a reasonable need methodology addressing those needs rather than the proposed, broad exceptions which completely swallow the general rule.

According to the most recently published report, the *2013 Kentucky Annual Hospital Utilization and Services Report*, there were 92 hospitals providing surgery services, with a total of 737 operating rooms. According to the Cabinet's May, 2015, *Inventory of Health Facilities and Services*, there were also 44 ASCs in Kentucky, with a total of 152 ORs. There are ASCs in eleven of Kentucky's fifteen Area Development Districts, including every ADD other than those in the easternmost parts of Kentucky. In fact, there are three ASCs in Owensboro alone.

Not only would proposed ASC Criteria 5 and 6 lead to a proliferation of unneeded ASCs, it would also increase the challenges to many hospitals, especially rural hospitals. Without a need methodology or any limit on the number or location of new ASCs, there will be a substantial risk that ASCs will be established in locations that will harm or even jeopardize the existence of some hospitals. It is well documented that many Kentucky hospitals are at risk of failing. Being burdened with the high cost of 24-hour services, indigent care, governmental programs paying less than cost, and other serious threats to their solvency, hospitals cannot afford to have more ASCs syphoning off some of the last remaining services that may provide a positive margin.

For all of these reasons, we request that the Cabinet delete proposed ASC Review Criteria 5 and 6.

II. MRI Services.

We oppose the Cabinet's proposal to remove MRI criteria from the 2015-2017 Kentucky State Health Plan. Again, this opposition is based upon quality concerns as well as the threat to existing providers, especially rural hospitals. Because of the statutory CON exemption in KRS 216B.020(1) for diagnostic centers that do not provide SHP covered services, removing MRI from the Plan would effectively remove any CON requirement for MRI facilities.

MRI, like surgery, is one of the few remaining services in which hospitals can make a positive margin to help cover other operating losses. The Cabinet's proposal would constitute another opportunity for others to skim some of the last remaining "cream" off the top and greatly jeopardize struggling hospitals. Anyone could establish a free-standing diagnostic center with MRI next door to any hospital, without a showing of need or the ability to provide a quality service.

The MRI criteria in the State Health Plan have not precluded approval of needed MRI services. However, they do make applicants demonstrate a need and ensure a minimum quality. Since 2009, there have been a number of applications for new MRI services that were approved. However, there were three that were disapproved. Of those, two were disapproved based upon an inconsistency with all statutory criteria, including need and quality of services. Indeed, the CON requirement has been useful in preventing poor quality providers from establishing MRI services. The Cabinet should keep MRI in the State Health Plan.

III. **Megavoltage Radiation Equipment.**

The Cabinet has proposed a definitional change and an adjustment of the minimum threshold requirements. We support those changes.

In Review Criterion 3 at page 53 of the 2015-2017 Kentucky State Health Plan, the Cabinet proposes to create a number of exceptions to the review criteria for applications by certain hospitals, or entities owned >50% by those hospitals. An application for a new radiation oncology program by any hospital or entity that falls within one of these exceptions would automatically be consistent with the State Health Plan, even if it is inconsistent with the need methodology. These exceptions do not include any limitation on how many such programs could be developed or where they could be located.

We oppose this change. Approval of additional radiation oncology programs should be tied to a need for such programs and the availability of existing programs in an area. In any event, if the Cabinet is going to adopt any exceptions to the need methodology, it should be limited to programs proposed by hospitals in the planning area and should require a demonstration of sufficient volume for a quality, cost effective program.

IV. **Special Care Neonatal Beds.**

We are a provider of Level II and Level III neonatal services. At pages 13 and 15 of the 2015-2017 Kentucky State Health Plan, the Cabinet has proposed clarifying language confirming that a Level IV provider that wishes to add Level II or Level III beds need not have an affiliation agreement with a Level IV provider. We support this change.

At pages 13-14, the Cabinet is proposing changes in Review Criterion 3. Criterion 3b would require an applicant for Level III beds to document that it has a neonatologist available 24 hours per day who is "able to be on-site within fifteen (15) minutes." We support this change, except that in many cases it may be very difficult to have a neonatologist who can be on-site within fifteen (15) minutes. Many hospital bylaws require that ER docs, general surgeons, interventional cardiologists, etc. be on-site within thirty (30) minutes. We request that the Cabinet change this proposal to require that Level III applicants demonstrate that a neonatologist is able to be on site within thirty (30) minutes.

Criterion 3c would require that applicants for Level III beds demonstrate that they will have a neonatal APRN on-site at all times when a neonatologist is not on-site. We support this change.

V. Home Health Agency.

At pages 35-37 of the 2015-2017 Kentucky State Health Plan, the Cabinet proposes three major changes to the home health criteria. First, they propose keeping the "need" criteria from the previous SHP. This methodology, based upon the comparison of county use rates per age cohort with state-wide rates, has been repeatedly demonstrated to be inaccurate. In fact, it identifies a "need" in many counties where there is clearly not a need, because the county use rates are below the state average due to a healthier, more educated population with higher income and greater access to alternatives. We suggest that if the Cabinet is going to modify the SHP requirements for home health, it first develop a more reasonable need methodology.

Instead of modifying the need methodology, the Cabinet has proposed creating three exceptions to that methodology. Proposed Criteria 4, 5 and 6 would allow applications by certain hospitals, by certain existing home health agencies and by ACOs or home health agencies affiliated with ACOs to be considered consistent with the State Health Plan notwithstanding the SHP methodology.

We would qualify under each of these three exceptions. However, we do not support this "planning by exception" approach. There are many counties in which there are already more than enough quality home health agencies to meet the needs of the patient and to give patients, their families and their physicians adequate choice. The Cabinet's proposal would not take into account the number or quality of existing agencies in a county. Therefore we oppose these changes.

CONCLUSION

Thank you for the opportunity to submit these written comments. As always, we support Kentucky's CON program and will continue to work with the Cabinet in the health planning process.

Sincerely,

Russ Ranallo
Vice President, Financial Services
Owensboro Health

The Christ Hospital Health Network

2139 Auburn Ave.
Cincinnati, OH 45219

513.585.2000

June 30, 2015

VIA E-MAIL

Ms. Emily Whelan Parento, Executive Director
Cabinet for Health and Family Services
Office of Health Policy
Division of Certificate of Need
275 East Main Street 4WE
Frankfort, Kentucky 40621

Re: Certificate of Need Modernization Program

Dear Ms. Parento:

I am writing on behalf of The Christ Hospital Health Network ("TCHHN") to formally comment upon the Cabinet for Health and Family Services, Office of Health Policy's proposed amendments to 900 KAR 5:020 State Health Plan for facilities and services. Specifically, The Christ Hospital applauds the Cabinet for Health and Family Services ("Cabinet") for undertaking this important task and supports amendments to the review criteria for Ambulatory Surgery Centers ("ASC") and Megavoltage Radiation Therapy Equipment ("MRT") because these modernizations to the Certificate of Need ("CON") program will improve the quality, access, and value of healthcare services in Kentucky. In addition, an amendment to the ASC review criteria and minor technical revisions are suggested, which are important to implement the proposed changes.

- **TCHHN supports the inclusion of quality factors as an evaluation tool for CON approval.**

Infusing quality of care as a factor in the evaluation of CON applications will increase the quality of care available for Kentucky citizens. The Cabinet's inclusion of data collected by the Centers for Medicare and Medicaid reported on its Hospital Compare Website as criteria for CON review will force all hospitals to pay close attention to their rankings and strive for better outcomes and quality.

TCHHN has a 126-year history of providing superior, high quality healthcare to the Greater Cincinnati community and the Tri-state area and is keenly aware of the importance of the

Medicare data. Hospital Compare focuses TCHHN's day-to-day attention upon quality and achieving, as well as exceeding, the national benchmarks. TCHHN desires to further expand its services in Northern Kentucky to make comprehensive, quality care more accessible to the growing number of Kentucky residents that our health system serves.

As Dr. Miller points out in his white paper "Inclusion of Out of State Hospitals in Kentucky's Certificate of Need Program" (Exhibit 1), areas in the Commonwealth exist where improvements in the quality of hospital care are desperately needed. The Cabinet's inclusion of these quality indicators is an important step toward raising the quality of care throughout Kentucky by incenting those hospitals that have achieved higher quality to expand their services and provide access to quality care. TCHHN urges the Cabinet to also consider CMS's readmission penalties as another measure of the quality of care provided by hospitals.

• TCHHN Supports the Proposed Amendment Adding ASC Review Criterion 5.

A documented need for additional ASCs exists in Kentucky. The 2015 Deloitte Healthcare Facility Capacity Report (the "Report") identified a growing trend toward outpatient health services and increased demand for ASCs, but also found that Kentucky lacks the facilities necessary to meet the needs of its population. The Report also found shortages that are expected to intensify as insurance coverage expands. Research documents that ASCs are the most cost-effective setting for outpatient surgery, but Kentucky has lower ASC utilization than national and regional benchmarks. For Kentucky, this means that even when an ASC is the appropriate and more cost-effective setting for a surgical procedure, the surgery is not performed in an ASC but rather is performed in a hospital.

TCHHN commends the Office of Health Policy's efforts to support the evolution of health care, improve access to care, improve value of care, and incentivize quality care through its amendments to the State Health Plan, which will create opportunity for quality hospitals to establish a new ASC provider. The current State Health Plan review criteria has handicapped healthcare providers in Kentucky by making it impossible to obtain a certificate of need ("CON") to establish an ASC when an applicant is required to meet planning area surgical utilization requirements[1]. Further, proposed ASC review criterion 5, which relaxes the review criteria for qualified hospitals, will allow more freestanding ASCs to be established and will have the effect of increasing competition and providing viable alternatives to hospital outpatient surgery department.

As Dr. Miller writes in "Inclusion Of Out Of State Hospitals In Kentucky's Certificate Of Need Program," allowing qualified hospitals to establish an ASC addresses a need to incentivize quality among existing healthcare providers. Recently, the Medicare program has considered quality of care in its hospital reimbursement formulas and concentrated on unplanned hospital readmissions within 30 days of a discharge from an acute care hospital as its key measure. Although the Medicare program recognizes that readmissions may be affected by factors that a hospital cannot control, the use of a 30 day rate rather than a longer period minimizes the other

[1] Of the 43 CON applications submitted since Jan 1, 2003, none were approved that had to meet the planning area surgical utilization requirements of the State Health Plan.

factors and provides an effective base for comparisons. Importantly in fiscal year 2015 (three years after the program started), two thirds of Kentucky hospitals received Medicare readmission rate penalties compared to a national average of 45 percent of hospitals[2]. Even more importantly, Kentucky hospitals had the highest average penalty among all states.[3] Proposed ASC Review Criterion 5 incentivizes quality by creating an opportunity for hospitals with distinguished quality ratings to establish an ASC. Specifically, proposed ASC Review Criterion 5 allows the establishment of an ASC, which is majority-owned (>50%) by a hospital if quality standards are met; each hospital with ownership interest must documents that it is performing "no different than" or "better than" the U.S. National Benchmark for 30-day outcomes for unplanned readmissions and 30 day death rates for select diagnoses as reported by CMS' most recently published Hospital Compare data.

In addition, proposed ASC Review Criterion 5 will allow quality hospitals, as indicated by its ability to meet quality indicator benchmarks, to more effectively compete in the health care market and bring a higher level of quality care to Kentucky. This resulting competition will encourage Kentucky hospitals currently to improve overall quality. TCHHN has established its interest in the Northern Kentucky region that is adjacent to its Ohio facilities by opening outpatient centers in the region. Like many hospitals across the U.S., TCHHN has steadily improved its 30 day readmission rate. As a result, in 2015, TCHHN was not penalized by the Medicare program, but rather awarded a bonus. If Kentucky CON requirements allowed TCHHN to more effectively compete in the Northern Kentucky region, it would bring a higher level of quality care to the area and the resulting competition would encourage Kentucky providers to improve overall quality.

Further, as explained by Dr. Miller, proposed ASC review criterion 5, will incentivize quality in a manner that will not harm rural hospitals, and, in fact, aid rural hospitals by creating opportunity for joint ventures and potentially introducing new physicians and surgeons to the region.

- **TCHHN Proposes Amending ASC Review Criterion 4.**

TCHHN proposes an amendment to ASC Review Criterion 4, which creates an exception to the planning area utilization requirement for an application to establish an ASC when the applicant demonstrates that a specific type of surgical procedure is not readily available to patients in a planning area. The amendment is as follows:

> 4. Overall surgical utilization in the planning area notwithstanding, an application to establish an ASC shall be consistent with this Plan if the following conditions are met.
>
> a. The applicant documents that patients are not receiving the specific type of surgical procedures (as identified by procedure codes) proposed by the applicant at facilities in the planning area; and

[2] Kaiser Health News, October 2, 2014, http://khn.org/news/medicare-readmissions-penalties-by-state/
[3] Id.

b. The application contains an explanation of why the unmet need for the specific type of surgical procedure has not been reasonably addressed by providers in the planning area;

The existing criterion indicates that an ensuing application must be limited to that specific type of surgical procedure. In other words, a CON application must propose to provide only the procedures that are not being performed. Because ASCs limited to a specific surgical procedure type are generally not financially sustainable, TCHHN proposes amending ASC review criterion to allow an applicant that has identified a specific type of surgical procedure as not readily available to patients in a planning area, and can explain why the unmet need for the specific surgical procedure type is not being met by existing providers, to establish a full-service ASC that provides the otherwise unavailable procedure in addition to other outpatient surgical procedures. Such a revision will allow a provider to meet the unmet need in a manner that is financially feasible.

- **TCHHN Supports the Proposed Amendment to the MRT Review Criteria for Quality Hospitals.**

For the same reasons stated above, TCHHN applauds the Cabinet's efforts to support the evolution of health care, improve access to care, improve value of care, and incentivize quality care by proposing amendments to the State Health Plan, which will create opportunity for quality hospitals to establish a comprehensive cancer center including megavoltage radiation therapy. As documented in previous comments filed by TCHHN, Kentucky is experiencing a cancer crises with not only a high rate of cancer incidence but the highest rate of cancer deaths in the nation. (Exhibit 2) These statistics indicate that not enough Kentuckians are benefitting from technology, like MRT, directed at treating cancer and improving rates of survival. TCHHN supports the Cabinet's proposed amendment to the MRT review criteria with the addition of review criterion 3 because it will allow accredited cancer programs to obtain the CON authority necessary to provide megavoltage radiation therapy, an important component of many cancer treatment plans. Further, relaxing the review criteria for accredited cancer programs will allow support the evolution of care deliver and improve access to care by allowing the establishment of comprehensive cancer care centers.

- **Suggested Minor Technical Revisions to ASC Review Criteria**

In addition, TCHHN recommends minor technical revisions to the punctuation in the ASC criteria. These suggestions, which are illustrated in the enclosed red-lined review criteria apply to ASC Review Criteria 5 and 6 and we believe to be necessary for the language to be implemented as intended by the Office of Health Policy.

- **Conclusion**

In closing, TCHHN appreciates the opportunity to participate in the Cabinet's modernization of the CON program. As a provider serving Kentucky patients, TCHHN is committed to improving the quality, access and value of healthcare in the Commonwealth. Please do not hesitate to contact us with any questions.

Sincerely,

Victor J. DiPilla
Vice President and Chief Business Development Officer
The Christ Hospital Health Network
2139 Auburn Avenue
Cincinnati, Ohio 45219
(513) 585-1295
Victor.DiPilla@thechristhospital.com

Enclosures

The Christ Hospital Health Network

#	*Date*	*Document*
1	12/11/14	Stakeholder Input in Response to Special Memorandum for Certificate of Need Modernization
2	03/19/15	White Paper: Certificate of Need Modernization in Kentucky By: Henry Miller, Ph.D.
3	06/26/15	White Paper: Inclusion of Out of State Hospitals in Kentucky's Certificate of Need Program By: Henry Miller, Ph.D.

APPENDIX 1

The Christ Hospital Health Network

2139 Auburn Ave.
Cincinnati, OH 45219

513.585.2000

December 11, 2014

Ms. Diona Mullins
Office of Health Policy
Cabinet for Health and Family Services
275 East Main Street, 4W-E
Frankfort, Kentucky 40621

Re: Stakeholder Input in Response to Special Memorandum for Certificate of Need Modernization

Dear Ms. Mullins:

As a stakeholder, The Christ Hospital Health Network ("TCH") is writing to formally respond to your Special Memorandum for Certificate of Need Modernization (the "Memorandum"). TCH has a 126 year history of providing quality health care services to the Greater Cincinnati community. While this service area has always included Northern Kentucky counties by serving Kentuckians at its downtown Cincinnati hospital and satellite outpatient centers in Ohio, in 2012 TCH began establishing healthcare facilities located in Kentucky. In its endeavor to make healthcare more accessible and more affordable to patients, TCH has become very aware of how Kentucky's certificate of need program both helps and hinders these efforts and appreciates the opportunity to respond as follows:

- **TCH supports the evolution of care delivery toward an outpatient-centric model**

As healthcare evolves, the roles of hospitals are changing to address the needs of patients and the demands of health care reform, Medicare and Medicaid, and the insurance payment systems or "payors." In fact, most traditional hospitals are evolving into integrated health systems that provide health care services nearly as much, if not more, in the outpatient setting as they do in the inpatient/traditional hospital setting. Further, hospitals are aligning with other health care providers to provide a full complement of services to patients.

TCH has a 126 year history of providing superior, high quality healthcare to the Greater Cincinnati Community and Tri-state area. The Tri-state area consists of a 14 county area that includes parts of Ohio, Kentucky and Indiana. Importantly, of the health systems and hospitals in this Tri-state area, TCH has been the most preferred system by consumers for the last 19 years. In addition, TCH has won many awards, is ranked by US News as one of the top 50 hospitals in the country, and has been named one of America's 50 best hospitals by Healthgrades, which is a national organization that measures quality based upon Medicare data and outcomes.

TCH is a not just a single downtown hospital, but has evolved into a health care network by expanding its hospital and its centers of excellence and developing a significant ambulatory/outpatient presence with physician divisions and the supportive services like laboratory, physical and occupational therapies, and the diagnostic/ancillary tools necessary for superior patient care. In delivering patient care, TCH concentrates on key clinical services with the goal of being a national leader in clinical excellence and patient experience.

TCH has developed physician offices in Kentucky located primarily in Kenton County and currently provides both primary care and specialist physician services that include orthopedic surgery, hematology/oncology, women's services, urology, cardiology, endocrinology diabetes, and recently implemented a CON-approved MRI, an important diagnostic service necessary to support TCH physicians and services in Kentucky. Through its outpatient centers, TCH strives to deliver basic healthcare services to the community in a manner that is convenient and cost-effective. Recognizing that many of its patients live or work in Northern Kentucky, TCH has been thoughtful in developing its Ft. Wright Outpatient Center so that the hours, location, parking, etc. are accommodating to its patients. Patients who have scheduled surgery at the hospital can receive most, if not all, of their pre-operative and post-operative services at the Ft. Wright Outpatient Center.

TCH wishes to further expand its services in Northern Kentucky in order to make comprehensive care more accessible to its significant Northern Kentucky patient population. Due to the current State Health Plan, the most efficient and appropriate method for developing a broad complement of services in Northern Kentucky has been through a piecemeal approach of CON-exempt facilities and services established as Special Health Clinics, as well as a laboratory and diagnostic imaging services. The Deloitte Study recognizes that comprehensive outpatient care improves the cost-effectiveness and quality of health care. Thus, TCH requests that the Office of Health Policy consider adopting a methodology through which health systems can provide more comprehensive, out-patient care as a single health facility. Moreover, TCH proposes the development of a single health facility type for multidisciplinary outpatient services including, but not limited to, emergency, primary, specialty, diagnostic, ambulatory surgery, radiation oncology, and diagnostic services, provided by a public or private provider-based institution with permanent facilities on a single campus and under the supervision of an organized medical staff.

- **By providing patient choice, TCH seeks to improve access, quality and cost of care in Northern Kentucky**

As the tremendous success of TCH's Fort Wright Outpatient Center demonstrates, Northern Kentucky Area Development District ("Northern Kentucky ADD") residents want additional capacity in terms of a choice of a provider for health services. Currently, St. Elizabeth is the only significant, provider of health services in Northern Kentucky. In fact, in Kenton, Campbell, and Boone Counties, St. Elizabeth Healthcare provides almost all the healthcare services that are available, including physician services. Simply put, there is no other health system that currently provides health care services in any of these counties. Since the merger of

St. Elizabeth and St. Luke Hospitals in 2008, St. Elizabeth has been essentially the sole health care system providing services in Northern Kentucky.

In Northern Kentucky, St. Elizabeth is the only provider of hospital services, the only provider of specialty services, almost the only provider of primary care services and cardiology services, as well as many other services. In short, St. Elizabeth has a monopoly in Northern Kentucky and has used the CON programs to sustain its monopoly as evidenced by its refusal to enter into a supportive relationship with TCH and aggressive opposition to TCH obtaining a CON to establish a MRI service in Kenton County. A sustained monopoly is not positive for Northern Kentucky and creates negative effects upon competition; consumer access to care, the health insurance market; recruitment and retention of physicians to the area and of course the price of services. By providing services in Northern Kentucky, TCH improves Northern Kentuckian's access to quality, affordable care by creating competition and patient choice. After all, it is undisputed that competition creates accountability and such market pressures force health providers to provide a better service at a lower cost.

- **TCH is committed to improving access to cancer care in Northern Kentucky**

Kentucky continues to be ranked 50th in the nation for cancer rates with an estimated cancer incident rate of 523.1 per 100,000 compared to the national average of 473.4 per 100,000. This indicates that we are leading the nation in one area of poor health and that there is a significant population of Kentuckians needing access to cancer care. Even more alarming, Kentucky also ranks 50th for cancer deaths with a cancer mortality rate of 211.3 as compared to the national average of 178.7. This means that not only are Kentuckians sick, but also they are not accessing the care that they need to survive cancer.

Radiation therapy, an integral part of a cancer patient's treatment and prognosis, is regulated via Kentucky's certificate of need program and in the State Health Plan. Of Kentucky's cancer deaths from 2005-2009, 52% were lung, breast, cervical and colon cancers, all of which typically receive radiation therapy as part of their aggressive treatment plan. For all persons diagnosed with cancer, research shows that 50% will receive radiation therapy as part of their treatment plan. Of those individuals, 88% will receive those radiation treatments through a linear accelerator, the equipment typically used to deliver megavolt radiation therapy. Moreover, each of those persons prescribed radiation treatment as part of their care plan will receive an average of 29 treatments as part of their therapy. The Kentucky Health Service Utilization Reports published by the Cabinet for Health and Family Services, however, demonstrates that Kentuckians are accessing megavolt radiation therapy at a rate much lower than what is indicated by these standards when applied to the incidence of cancer in Kentucky, as reported by the Kentucky State Cancer Registry. Further, the Deloitte Study recently commissioned by the Cabinet for Health and Family Services and Kentucky Health Benefit Exchange, The Commonwealth of Kentucky Health Care Facility Capacity Report, emphasizes that compared to baseline benchmark data, Kentucky has 10% lower utilization of megavolt radiation equipment when compared to other southern states.

Kentucky's underutilization of life-saving cancer treatment is especially evident for the population in the Northern Kentucky ADD:

Northern Kentucky ADD, 2012

	Population	Cancer Incidence (0.5%)	Radiation therapy eligible (50%)	LINAC indicated (80%)	LINAC procedures (29 treatments/patient)
Projected Utilization	448,509	2,243	1,122	897	26,013
Actual Utilization	[redacted]				8,392
Difference					17,621

Due to the high number of projected cancer treatments with comparison to the current utilization, it is apparent that Kentuckians need greater access to cancer treatment programs than what is currently available.

Kentucky's high rate of cancer, low access to cancer treatment, and high rate of cancer mortality demonstrate that changes to the current State Health Plan are necessary for the welfare of Kentucky patients. Additionally, research illustrates a growing need for cancer care due to increased incidence and anticipated capacity limitations. The American Cancer Society estimated that the United States would have an additional 1,660,290 new cancer cases in 2013, which would result in an additional 580,350 cancer deaths. Further, the Deloitte Study found that between 2012 and 2017 there will be a 5-9% increase in demand for megavolt radiation services and that there will be capacity constraints in at least two of Kentucky's eight Medicaid Managed Care Regions ("MMCR") by 2017. Based on TCH's experience, we believe that MMCR 6- Northern Kentucky is already suffering a capacity issue as a significant number of cancer patients from this region are currently migrating out of Kentucky to Ohio for treatment at TCH.

The need for improved access to cancer care is clear. As stated by The Kentucky Cancer Foundation co-founder, Dr. Whitney Jones: "Kentucky leading the nation in overall cancer mortality is no longer acceptable. This is our problem, we own it." This call to action has resonated with Governor Beshear and his efforts to improve the health of Kentuckians. TCH supports changes to the State Health Plan criteria for megavoltage radiation therapy services that will enable the Certificate of Need Program to better serve its purpose of improving the quality of, and increasing access to, health care facilities, services, and providers while creating a cost-efficient health care system for the citizens of the Commonwealth. In addition to cancer care services provided at TCH's hospital and outpatient centers in Ohio, TCH currently provides hematology, oncology and infusion (e.g. chemotherapy) services in Kenton County and believes there is a clear need for more comprehensive cancer care, specifically access to radiation services

provided by a linear accelerator. Thus, TCH encourages the Office of Health Policy to revise the megavoltage radiation therapy review criteria, as recommended in the Deloitte Study.

- **TCH is committed to improving access to outpatient surgical care in Northern Kentucky**

For about two decades, the State Health Plan review criteria for ambulatory surgery centers ("ASC") have remained unchanged. Further, the current review criteria essentially places a moratorium on the establishment of these facilities in Kentucky even though they have proven to be the far more cost effective alternative when compared to hospital outpatient departments for outpatient surgery. We agree with the Deloitte Study's finding that such regulation is detrimental to healthcare in Kentucky and should be revised. Of the 43 ASC applications submitted since January 1, 2003, that had to meet the planning area surgical utilization requirements of the State Health Plan, none were approved—this fact alone commands that the criteria be revised to improve access to ambulatory surgery centers. Thus, even though the benefits of improved access to outpatient surgery care have become clearer over the past decade, Kentucky health policy has prevented the establishment of new ASC's.

As a health system providing inpatient and outpatient surgery services in Ohio, we have identified some issues with the way in which the current methodology measures operating room utilization that has resulted in the misrepresentation of actual utilization. For instance, we recognize the fact that not every surgery provider operates every one of its operating rooms. This can be due to a number of factors, including, but not limited to strict licensing requirements related to the basic infrastructure and health and safety codes. Further, operating rooms are managed so that some rooms are purposefully left out of service yet equipped and ready to accommodate emergencies. As a result, there are more operating rooms in existence in Kentucky than are in operation. This distorts your office's ability to measure actual utilization. For example, in Kenton County, there is a hospital that reports the existence of 19 operating rooms, yet last year, it reported only 7,900 total surgery procedures. In other words, assuming all of the operating rooms are operational, these operating rooms are averaging about 500 procedures per year or each procedure performed in these rooms is averaging about 5 hours per surgery. This does not reflect reality. Clearly, not all of these rooms are operational on a daily basis and it is essential that the State Health Plan be revised to adopt a more accurate measure for determining need for ambulatory surgical services. Further, we support the adoption of a methodology for assessing need that considers the cost-effectiveness and additional benefits of outpatient surgical care when appropriate for the patient.

- **TCH seeks to improve access to care for Medicaid beneficiaries**

For a number of reasons, Medicaid members have, on average, a more challenging path toward access to care. As a result of the Affordable Care Act ("ACA") and through the expansion of Kentucky's Medicaid program, health insurance coverage has become available for a significant population of previously uninsured individuals in Northern Kentucky and TCH's Primary Service Area ("KPSA"). To provide care to this previously uninsured population, TCH

must expand its services to meet patient needs in a cost effective manner. By expanding its outpatient health services, including cancer treatment and ambulatory surgery, TCH will be able to manage the needs of these individuals in a cost-effective, patient-centered, high quality manner.

- **Conclusion**

Improving access to comprehensive care can be accomplished only by carefully reviewing and revising the applicable State Health Plan review criteria and considering the health status of the Commonwealth as a whole. Thus, TCH requests that the Cabinet take into consideration these proposed changes, which we believe will assist the Commonwealth in its mission of achieving improved access to quality healthcare. Thank you for your attention. Please do not hesitate to contact us with any questions or requests for additional information.

Sincerely,

Victor J. DiPilla
Vice President and Chief Business Development Officer
The Christ Hospital Health Network

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APPENDIX 2

CERTIFICATE OF NEED MODERNIZATION IN KENTUCKY

March 19, 2015

Prepared by:
Henry Miller, Ph.D.
Berkeley Research Group, LLC.
And
The Christ Hospital Health Network
Cincinnati, Ohio

CERTIFICATE OF NEED MODERNIZATION IN KENTUCKY

1. PURPOSE OF THIS PAPER

In October 2014, the Cabinet for Health and Family Services (the Cabinet) requested stakeholder input regarding the modernization of the Commonwealth's Certificate of Need (CON) program. The Cabinet recognizes that the Kentucky health care system, like systems throughout the U.S., is undergoing substantial changes. CON laws were originally established in the 1970s when cost containment concerns focused on unnecessary duplication of inpatient hospital services. Changes in health care delivery over the past several years slowed the growth of inpatient services while outpatient services grew rapidly. Recently, passage of the Affordable Care Act and other factors further changed the health care systems environment. The need to consider the effects of these changes led the Cabinet to investigate modernization of its CON program.

When it requested stakeholder input, the Cabinet identified Core Principles to guide its consideration of changes in the CON program. These principles, which reflect the environmental changes that the health care system is experiencing, are:

- Supporting the Evolution of Care Delivery,
- Incentivizing the Development of a Full Continuum of Care,
- Incentivizing Quality,
- Improving Access to Care,
- Improving Value of Care,
- Promoting Adoption of Efficient Technology, and
- Exempting Services for which CON is no longer necessary.

This paper has been prepared to provide feedback to the Cabinet. It includes additional descriptions of the Core Principles and identifies the key issues that will underlie the future of Kentucky's CON program. In addition, it recommends changes to the Commonwealth's CON program that will be needed to meet the Cabinet's modernization goal.

2. THE NEED FOR MODERNIZATION

At one time, all 50 states had Certificate of Need laws aimed at containing health care costs and improving access to care by regulating changes in state health systems. Although some states repealed their CON laws, Kentucky is one of 36 states that retained CON requirements, although these requirements vary substantially from state to state.[1]

For example, all states with CON programs regulate changes in nursing home and other long-term care beds. However, eight of the 36 states with CON programs have discontinued regulation of acute care beds; nine of these states do not regulate ambulatory surgery centers; ten do not regulate cardiac catheterization programs; 18 do not regulate home health and hospice care; 21 do not regulate Mobile Technology (CT/MRI/PET); 18 do not regulate magnetic resonance imaging scanners; 13 do not regulate

[1] National Conference of State Legislatures, "CON – Certificate of Need Laws" at http://www.ncsl.org/research/health/con-certifictate-of-need-state-laws.aspx.

radiation therapy and 17 do not regulate substance/Drug Abuse programs. Kentucky includes all of these services in its CON program.[2]

The debate about the effectiveness of CON programs began when the programs were first initiated in the 1970s. Proponents argued that regulation was the best approach for containing rising health care costs and assuring access. Opponents argued that competition more effectively met these goals. As proponents and opponents of CON programs continued to advocate their positions, changes in the U.S. health care system occurred. Utilization of inpatient acute care services declined substantially when the Medicare program introduced case-based prospective payment. At the same time, outpatient service volumes increased dramatically, which led to increased attention paid to these services by state CON programs.

Other important health care system changes also occurred. Hospitals concerned about their financial survival or seeking to gain leverage in private sector payer rate negotiations began to join together to create hospital systems. The growth in outpatient service volumes also led these systems to purchase or create outpatient programs including ambulatory surgery centers, freestanding diagnostic centers and home health agencies. These systems often sought to provide services through the entire continuum of care.

Outpatient care growth in hospital-based and other health care systems has accelerated since the Affordable Care Act (ACA) was enacted in 2010. The ACA's focus on the Triple Aim defined by the Institute for Health Improvement[3] provided new opportunities for health care systems to assume risk for the populations they serve through organizational changes (e.g., Affordable Care Organizations) and new payment methods aimed at promoting quality.

The emerging health care system provides promise for improvements. As providers assume more risk for the health of the populations they serve, they will be incentivized to improve the quality of their services. As providers assume more financial risk through innovative payment methods, they will be incentivized to contain cost and increase the value of the services that they provide.

3. ISSUE

The Core Principles recognize the changes in the health care system that have occurred and are continuing to occur. The Cabinet must decide whether the Core Principles can be best achieved through continued regulation or through competition among providers. This decision requires the Cabinet to answer several questions, including:

- Can insights be gained from prior studies of the effectiveness of CON regulation?
- Is there a market that allows competition to be effective?
- Will changes in methods for paying providers be sufficient to achieve the Core Principles?
- Is regulation needed to protect quality of care and sole community providers?

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[2] Id.

[3] Institute for Health Care Improvement, "IHI Triple Aim Initiative" defines the Triple Aim as improving the patient experience of care (including quality and satisfaction, improving the health of populations and reducing the per capita cost of health care. See: http://www.ihi.org/Engage/Initiatives/TripleAim/pages/default.aspx.

4. PRIOR STUDIES OF THE EFFECTIVENESS OF CON REGULATION ARE NO LONGER RELEVANT

Studies of the effectiveness of CON regulation have not been conclusive. Some studies found that CON regulation is effective in controlling cost while others found that competition is more effective.[4] These studies are no longer relevant. For the most part, they were completed between ten and twenty years ago and evaluated a different health care system than the one that exists today and will exist in the future.

Moreover, it is not surprising that studies of the effectiveness of CON have been inconclusive. Substantial excess acute care capacity was created across the U.S. when the Medicare program introduced case-based prospective payment. Hospitals responded rapidly to prospective payment by dramatically reducing patients' average length of stay. The reduction in average length of stay from 1980 to 1990 varied by region but was as great as 40 percent.[5] These reductions created large numbers of unused beds in all states, regardless of whether or not they had CON regulations.

The Cabinet must make its decisions in light of today's health care system and not based on past issues and concerns.

5. THERE IS A MARKET THAT ALLOWS COMPETITION TO BE EFFECTIVE

In its submission to the Cabinet, the Kentucky Hospital Association argued that there is no real market for health care services.[6] It may have been true that an effective health care market didn't exist when CON regulations were developed, but health care markets are rapidly evolving. A functioning health care market requires patients to have sufficient information to make choices when they seek care. It is especially important for patients to have information on physicians, since physicians frequently determine which hospitals or outpatient facilities a patient will use. Patient satisfaction, patient perceptions of quality and price of care all affect a patient's choice of physician. The Internet has led to rapid growth in the availability of information on these factors. For example, the widely used Healthgrades© web site offers information on patient satisfaction and quality of care indicators such as education, board certification and incidents of malpractice. The site also offers grades on hospital care. A growing number of health plans are offering information on physician and other provider costs on their web sites. As this information is increasingly used, the opportunity for market based decisions grows.

In addition, when the CON program was initiated, the focus of health care system growth was on building costly new acute care beds which meant that competition among providers for these beds had substantial risk and often, it wasn't clear that their construction sufficiently improved access to care to justify their need. Today, the trade-off between access and costs has changed. Health care system growth now focuses on expansion of less costly outpatient services. Competition among providers to develop outpatient services has lower risks for the Cabinet's efforts to contain costs.

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[4] Add FTC/DOJ and auto manufacturers studies.

[5] See Mark R. Chassin, "Variations in Hospital Length of Stay: Their Relationship to Health Outcomes," Health Technology Case Study No. 24, Office of Technology Assessment, Washington, DC, 1983 and "Inpatient Hospital Stays and Length of Stay", HCUP Facts and Figures, Agency for Healthcare Research and Quality, 2009.

[6] Daniel J. Sullivan and Kentucky Hospital Association, "Certificate of Need: Stabilizing Force for Health Care Transformation", December 2014.

The Cabinet must make its decisions with the understanding that the market for health services exists and it will allow competition to be effective in controlling costs and improving access.

6. CHANGES IN METHODS USED TO PAY PROVIDERS WILL NOT BE SUFFICIENT TO ACHIEVE THE CORE PRINCIPLES

In its submission to the Cabinet, the Kentucky Hospital Association also argued that changes in methods used to pay providers will be sufficient for the Core Principle of improved value to be achieved.[7] Methods by which providers are rewarded for improved quality, increased attention to accountable care and population based payment were noted. Medicare is leading the way on these approaches, but Medicare will not be effective in today's environment unless its efforts are complemented by similar efforts by health plans. When Medicare introduced prospective payment in 1983, its focus on inpatient acute care was especially effective because Medicare beneficiaries accounted for the greatest number of inpatient acute care patients. As noted, acute care volumes have declined proportionally and outpatient volumes have grown. Medicare beneficiaries make up a relatively small portion of outpatients which means that health plan involvement is needed to assure new payment changes are effective.

In some parts of the U.S., health plans are seeking similar opportunities to change payment methods. Health plans, however, cannot implement payment system changes without competition. Unless health plans have opportunities to select among providers who seek to contract using the new approaches, providers will be able to obtain high rates, regardless of the payment approach that is used. Moreover, there will be no incentive for health plans to contract at these high rates and existing payment systems will remain in effect.

The Cabinet must make its decisions with the understanding that new payment methods will only be effective if health plans can seek contracts with competing providers.

7. REGULATION IS NOT NEEDED TO PROTECT QUALITY OF CARE AND SOLE COMMUNITY PROVIDERS

In its submission, the Kentucky Hospital Association concluded that quality of care will be protected by continued CON regulation.[8] Continuing CON regulation will provide protection, but not protection of the quality of care. Instead, Kentucky's existing hospitals and hospital systems will be protected. Regulated entities seek to maintain regulation when they seek protection from potential competitors. This concept of regulatory capture is well documented in the economics literature.[9] The Hospital Association is asking the Cabinet to use CON regulation to keep competitors from challenging the "franchises" they have built.

If CON regulation is used to protect the franchises of existing hospitals and health systems, there is potential for Kentucky's health care system to stagnate. Changes in Medicare payment methods may encourage innovation in the development of a broader continuum of care, but without competition,

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[7] Id.
[8] Id.
[9] See, for example, http://online.wsj.com/articles/regulatory-capture-101-1412544509.

innovations will take whatever form existing hospitals and health systems decide to implement. They will have little incentive to innovate beyond the easiest and simplest approaches.

There is also little potential for improvements in quality without competition. The Hospital Association argues that higher quality services are provided in high volume facilities. They conclude that therefore, services should be provided in as few places as possible, to protect volumes. Places however, do not perform services, physicians and other professionals provide services. The relationship between quantity and quality cited by the Hospital Association is misused. There is evidence that the more frequently a surgeon performs a procedure, the better he or she gets at that procedure. This finding, however, is derived from the competitive environment present in most states. Surgeons that are especially effective in performing a procedure attract additional patients and their familiarity with the procedure grows until they are exceptionally good at performing the procedure. The number of times a procedure is performed in a hospital is not relevant since surgeons who perform procedures frequently and those that perform them infrequently may all use the same hospital.

There is evidence that quality may, in fact, suffer when services are concentrated in a single facility. For example, King's Daughters Medical Center in Ashland is the only local hospital that has a CON approved and operational for a comprehensive cardiac catheterization service. In 2013, the Federal government began an investigation of unnecessary percutaneous coronary intervention (PCI) procedures at King's Daughters. The government found that unnecessary procedures had been performed on Medicare patients between 2006 and 2011. King's Daughters paid a substantial civil penalty. Due to King's Daughters Medical Center's strong opposition to competition in the market, another hospital in the market was unsuccessful in obtaining a CON to provide the same service until 2014. In this case, CON regulation did not result in improved quality even though a high volume of services were provided in a single hospital.

The Hospital Association also describes the need to protect sole community hospitals from competitors who will capture their patients who have commercial coverage and leave only the poorly paying Medicare and Medicaid patients for the sole community providers who cannot survive financially unless they have these better paying patients.[10] Unfortunately, sole community providers struggle to survive financially and have been doing so for many years. It is unlikely, however, that competitors will enter their region to compete with them. Kentucky's sole community hospitals do not provide surgical services so if a new ambulatory surgical center was opened in their region, it would not compete. The only service that sole community hospitals provide that could be subject to competition would be Emergency services. The very low volumes of emergency services provided by most of the Commonwealth's sole community hospitals, however, would not be sufficient to attract competitors.

8. SUCCESSFULLY ACHIEVING THE CORE PRINCIPLES REQUIRES COMPETITION

As noted, the Cabinet identified seven Core Principles for the modernization of CON:

- Supporting the Evolution of Care Delivery,
- Incentivizing the Development of a Full Continuum of Care,
- Incentivizing Quality,
- Improving Access to Care,
- Improving Value of Care,

[10] Sullivan and Kentucky Hospital Association, op. cit.

- Promoting Adoption of Efficient Technology, and
- Exempting Services for which CON is no longer necessary.

The evolution of care delivery has led to the reductions in inpatient services and the growth of outpatient services that have been described. There are continuing needs to encourage the growth of outpatient services. Continuation of CON requirements for outpatient services such as ambulatory surgery centers and freestanding diagnostic centers will limit their growth and constrain efforts to contain costs and improve quality. Competition, not regulation, is needed to support the evolution of care delivery.

If CON regulation is used to limit the introduction of new competitors in the Commonwealth's health care system, incentives to develop a full continuum of care will affect only existing providers. Hospitals and health systems may elect to develop a full continuum of care, but if they do, they will not have incentives to assure the value and quality of the services they provide. Instead, they will be incentivized to increase the size of the continuum of care they offer without having to be concerned about value and quality.

The importance of using competition to incentivize quality has been stressed in earlier discussions in this paper. Continuation of CON regulation will give existing providers the opportunity to establish quality standards that will, at best, be at a lower level than the standards that would be developed through competition.

Competition improves access to care. New competitors seek environments where there are sufficient patient populations that they need to succeed. Access in these environments can only be improved.

Continued CON regulation will limit entry into Kentucky's health markets and will support monopoly and monopsony opportunities for providers. Improvements in the value of care will depend on the willingness of hospitals and health systems to make investments in care although there will be few penalties if they fail to do so. If hospitals and health systems are required to assume responsibility for the health of the populations they serve, they will be incentivized to provide increased value. Although population health is receiving increased attention, it will be many years, at best, before hospitals and health systems suffer penalties for not maintaining the health of their populations. Competition, on the other hand, offers immediate opportunities for improvements in value.

It is difficult to use CON regulation to promote the use of efficient technology. CON regulators can identify efficient technologies and inform providers that they will approve its use, but they cannot require such technology to be developed and used. When a competitor offers newer and more efficient technology, it provides a strong incentive for other competitors to follow suit. Competition, rather than regulation, promotes the use of efficient technology.

Kentucky's health care system will be best served by discontinuing CON regulation and letting competition foster achievement of the Core Principles. The opportunity for competition to improve value, promote access and incentivize improved quality of care may not have existed when CON regulations were originally implemented, but the changes that have occurred mean that there are real opportunities to improve the Commonwealth's health care system by encouraging competition.

APPENDIX 3

INCLUSION OF OUT OF STATE HOSPITALS IN KENTUCKY'S CERTIFICATE OF NEED PROGRAM

June 26, 2015

Prepared by: Henry Miller, Ph.D.
Berkeley Research Group, LLC

INCLUSION OF OUT OF STATE HOSPITALS IN KENTUCKY'S CERTIFICATE OF NEED PROGRAM
Prepared by Henry Miller, Ph.D.

1. INTRODUCTION

This brief paper discusses whether out of state hospitals should be included in the Kentucky Certificate of Need (CON) program and the likely impact that their inclusion will have on quality of care and rural hospitals.

There are areas of the Commonwealth where improvements in the quality of hospital care are critically important. In recent years, the Medicare program has considered quality of care in its hospital reimbursement formulas. It has concentrated on unplanned readmissions within 30 days of a discharge from an acute care hospital as its key measure. Although the Medicare program recognizes that readmissions may be affected by factors that a hospital cannot control, the use of a 30 day rate rather than a longer period minimizes these other factors and provides an effective base for comparisons. It is important to note that for fiscal year 2015, two thirds of Kentucky hospitals received Medicare readmission rate penalties (compared to a national average of 45 percent of hospitals).[1] Even more importantly, Kentucky hospitals had the highest average penalty among all states.[2] For this reason, this paper focuses on 30 day readmission rates as the key quality measure considered.

2. IMPACT OF INCLUSION OF OUT OF STATE HOSPITALS IN CON REQUIREMENTS ON QUALITY OF CARE

Inclusion of out of state hospitals in Kentucky's CON requirements provides opportunities to improve quality of care in the Commonwealth. Although Kentucky's hospitals have maintained average quality standards, regions of the Commonwealth, including regions that are adjacent to other states, can be substantially improved.

When Medicare readmission rates were introduced, a large portion of the Nation's hospitals incurred penalties. Most recognized needs to improve and undertook programs to reduce readmissions. As a result, the majority of hospitals have had reduced rates over the three year period from 2013 to 2015. Although failing to reduce readmission rates has an impact on Medicare reimbursement, when a hospital system is the sole provider for a geographic area, the poor quality ratings and penalties do not affect a hospital's efforts to retain all patients in the region since there are no competing hospitals.

If Kentucky CON requirements allowed out of state hospitals or Cross Line Hospitals to more effectively compete in Kentucky, it would bring a higher level of quality care to Kentucky and the resulting competition would encourage Kentucky hospitals currently without or with limited competition to lower readmission rates and improve overall quality.

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[1] Kaiser Health News, October 2, 2014, http://khn.org/news/medicare-readmissions-penalties-by-state/
[2] Id.

Inclusion of out of state hospitals in the Kentucky CON program can contribute to quality of care and access to services in other ways as well. State borders do not define health care service areas. In regions where a metropolitan area crosses state lines, many physicians are licensed in each of the states included in the region. Opportunities for out of state hospitals to participate in the CON program mean that these hospitals can increase the number of primary care physicians and specialists who practice in the region. The presence of these physicians also affects competition, which, in turn, improves quality.

3. IMPACT OF INCLUSION OF OUT OF STATE HOSPITALS IN CON REQUIREMENTS ON RURAL HOSPITALS

It is unlikely that including out of state hospitals in the Kentucky CON program would have a negative impact on rural hospitals. First, out of state hospitals are most frequently located near metropolitan areas and currently serve out of state patients that live in their metropolitan area. When entering an adjacent state, they are seeking to provide services more conveniently to these patients and other similarly located patients. Second and most importantly, both for profit and not for profit out of state providers are interested in areas that provide sufficient patient flows for their programs. Out of state providers that are seeking opportunities in Kentucky are not going to locate in rural areas where available patient populations cannot support their programs.

Including out of state hospitals in the Kentucky CON program, however, can positively affect rural hospitals. Rural hospitals need to continue their conversion from inpatient to outpatient providers. In many cases, however, they do not have the resources to develop outpatient programs that may be needed in their communities. They may look to hospital systems in urban and suburban areas to join with them to offer new programs. Such programs have substantial risks, however,(because of low volumes) which limits the number of potential joint venture partners. The addition of out of state hospitals to the pool of interested providers makes it more likely that joint ventures can be carried out.

Outpatient expansion by rural hospitals is also frequently constrained by a lack of physicians. For example, many rural hospitals have stopped providing surgical services because they do not have surgeons who are practicing in their area. In-state hospitals have taken only limited action to encourage surgeons and other specialists to practice in Kentucky's rural areas. Out of state hospitals who are interested in establishing programs in Kentucky may be helpful in bringing new physicians to rural areas.

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June 29, 2015

Emily Parento
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Dear Ms. Parento,

I wanted to take this opportunity to request a few considerations as it relates to the May 2015 Draft 2015 - 2017 State Health Plan ("Plan"). First, I applaud your efforts to make some changes to the Plan, many provisions of which have not changed in decades. The CON Modernization efforts and the SIM project all clearly reflect an effort on behalf of the Cabinet to ensure our state is responding to the rapidly changing healthcare environment and preparing us for future expectations.

Special Care Neonatal Beds

As a neonatal provider across all Levels of care, Norton appreciates the clarifying language inserted for Level II and III providers who also meet Level IV criteria to no longer require a written affiliation agreement with a provider who meets Level IV criteria.

We also noted that the criteria for a Level III provider was modified to no longer require a neonatologist be on-site 24 hours per day but would allow that provider to be 'continuously available 24 hours per day and able to be on-site within fifteen (15) minutes.' While the Guidelines for Perinatal Care are not completely specific, they do state that Level III providers are those "having continuously available personnel (neonatologists, neonatal nurses, respiratory therapists)..." Norton supports the Cabinet's recommended change but would raise safety concerns if the time to be on-site is extended beyond the fifteen (15) minutes currently recommended. As these are highly fragile infants, we believe that time is of the essence to ensure survivability and the best quality of life for the child.

Megavoltage Radiation Equipment

Norton understands, and is supportive of, the change to consider only those CON's issued within the last three years. However, new criteria #3 states that ANY hospital that meets one of the accreditation criteria noted will have an ability to implement radiation therapy services, irrespective of the need. As the planning area is limited to Kentucky counties, we recommend that this exception also be limited to Kentucky hospitals. There are 984 programs across the country that meet one of these accreditation certifications. While it may not be practical to consider the opportunity that each of these providers might have to serve our community, there remain more than 40 accredited programs in the state of Kentucky and within 100 miles in surrounding states. This exception opens our borders for a significant number of providers to add services in Kentucky, without having to demonstrate any need.

We believe strongly that there should be a need calculation prior to entry of new providers in the state to prevent proliferation and duplication of services. Linear Accelerator procedures peaked in 2011 with 225,628 procedures, but have declined in the subsequent years, according to the state utilization reports.

On the surface, this certainly indicates that there remains capacity with existing providers across the state to serve Kentuckians.

Ambulatory Surgical Center

Review of the proposed changes to the Ambulatory Surgical Center raises some questions as to consistency. Criteria #3 retains the requirement of new ASC's to be located within 20 minutes of at least one acute care hospital but eliminates the requirement to have a transfer agreement in place.

Additionally, the licensure regulation (902 KAR 20:106) includes two provisions related to acute care, which require the licensee to include a policy that provides "arrangement for transportation of patients who require hospital care" and to require the Center to "have a physician on the medical staff with admitting privileges in a nearby hospital who is responsible for admitting patients in need of inpatient care."

Norton requests the Cabinet to consider modifying the new proposed criteria #5 which allows "a hospital" that meets certain quality criteria to establish an ASC, to add language that allows this exception for Kentucky hospitals AND to add a provision that would ensure the ASC is to be located in a county or contiguous county to the applicant hospital. This would help ensure that patients have access to appropriate urgent care, if needed.

Outpatient Health Care Center

We request some clarity around the removal of this service from the State Health Plan. As I understand it, removal from the State Health Plan does not eliminate the need for a CON but does move the process to non-substantive review. This, obviously, greatly reduces the time to establish such a site and may provide a good option for rural hospitals to convert. However, the licensure regulation states that this type of facility must be:

> (i) provider-based according to CMS, which means it must be affiliated with a licensed acute care provider,
>
> (ii) in a county with no hospital,
>
> (iii) in an area that has a population of 60,000 or more persons, and
>
> (iv) in a medically-underserved area as determined by the Secretary of the Federal Dept. of Health and Human Services.

Is it the Cabinet's intent to modify any of the criteria above to allow a rural facility convert to a different license? If the requirement remains to be affiliated and be subordinate to their Main Provider, will that require the facility to satisfy this through an affiliation with a tertiary provider in the state?

Upon review of the Medically Underserved Areas designated in Kentucky, there are several counties that have full county designation as a MUA, but there are close to twenty (20) counties that have selected census tracts with MUA designations. Although these counties do have a hospital currently, will this criteria be excepted if it's a conversion of an existing hospital and thereby allow these areas to convert their facilities as well if they so choose?

Additionally, if a hospital facility converts to an Outpatient Health Care Center, will they be able to retain their acute care beds and reinstate for another reason if the need arises? As Kentucky is a rapidly aging

state and the Medicare population heavily utilizes long-term care services, there could be a use for these beds in a different capacity. Retaining this option would potentially eliminate, or certainly reduce, future capital spending if these units were converted to long-term care. Further, this would meet a community need and retain a highly skilled workforce.
The formal review CON process required the applicant to document funding sources, which would not be required under the non-substantive review process. Although the capital would, theoretically, be minimal, I think it is important to ensure the provider is financially stable to continue to provide such services in a different setting.

Lastly, we applaud the Cabinet's efforts to incorporate some quality standards in various areas of the State Health Plan. However, quality or performance metrics are not delineated in the licensure regulation for Outpatient Health Care Centers and are not part of the non-substantive review. We request consideration of some quality measurement for this category of service as well, as it would be a comprehensive ambulatory provider in the community.

We appreciate the opportunity to comment on the changes and look forward to working with the Cabinet as we transition our state and service offerings.

Sincerely,

Mary Jo Bean

Bean, Mary Jo
Vice President, Planning & Business Analysis
Norton Healthcare, Inc.

cc: Steve Williams, CEO
Mary Michael Corbett, Vice President, Government Relations
Dustin Meek, Tachau Meek Law

St. Elizabeth HEALTHCARE

Garren Colvin, President and Chief Executive Officer

June 29, 2015

Ms. Tricia Orme
Office of Legal Services
275 East Main Street 5 W-B
Frankfort, KY 40601

Dear Ms. Orme:

Thank you for the opportunity to provide comments on the proposed changes to the State Health Plan (SHP). St. Elizabeth Healthcare (St. Elizabeth) understands the need for the Cabinet to modernize the plan criteria to adjust for the changes facing our healthcare system and further improve the health of Kentuckians. The Certificate of Need process ensures that residents of the Commonwealth have access to care and prevents the proliferation of unnecessary or duplicative services that add to the cost or reduce the quality of the healthcare system.

We support the general concepts of modernization as they are aligned with the triple aim. However, we are concerned that the modernization efforts have been primarily focused on reducing the number and type of services that are allocated based on "community need" via the CON process. This focus will have the unintended consequence of destabilizing the market and negatively affecting existing safety-net providers like St. Elizabeth and many hospitals across the Commonwealth.

The CON process creates the stabilizing force that (1) assures access, quality and efficiency; and (2) allows for competition on a level playing field. These are the two overriding principles that must govern all of the proposed changes. We applaud the requirement for providers to set forth a plan to care for caring for underserved populations; however, we have concern that there are currently no mechanisms that would ensure that providers met their stated obligations towards low- or un-compensated care. We also concur with many of the Cabinet's changes to the State Health Plan that expand access to post-acute care, but believe additional refinement is necessary to expand these services appropriately.

We would like to focus our comments, however, on three changes made to the plan that run counter to the stated ideals of the modernization intent of the Cabinet: Ambulatory Surgery Centers (ASC), Megavoltage Radiation Therapy, and Outpatient Centers, the Cabinet should retain the criteria as set forth in the *2013-1015 State Health Plan.*

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AMBULATORY SURGERY CENTERS & RADIATION THERAPY

Primarily, St. Elizabeth does not the support the proposed changes to ASC and Radiation Therapy criteria that allow a provider to establish a service regardless of the need for the service in the geographic area, simply by meeting certain quality criteria. A need methodology that takes into account projected volumes and existing capacity, and is important to ensure quality, access, and efficiency in a market. Additionally, the "need" criteria are part of the enabling statute for the SHP. As such, the removal of these criteria from some of the SHP seems counter to legislative intent.

"Need" Criteria Ensures Quality

St. Elizabeth supports modernization efforts that seek to incorporate quality standards into the evaluation of services, but this effort needs to be in concert with establishing a "need" for the service in the geographic area. In fact, need and quality are inextricably linked. There is significant evidence in many clinical areas that sufficient volumes are required to adequately maintain staff competency levels and quality of care. In areas where there is ample existing capacity, adding additional capacity will only dilute volume and affect quality.

For example, cancer programs need a certain level of volume to be able to provide all of the necessary services that complement and support the patient in their care and recovery, such as navigation staff, support groups, and counseling. Without a sufficient level of cases, these services cannot always be maintained. However, these services are critical to the continuum of quality care. At the present time, there is not a need for additional facilities in the Northern Kentucky region. In addition, some radiation patients require fewer radiation therapy treatments because of new technologies that better targets cancer cells, and new studies that show that fewer fractions can be effective. Given this reduced need for treatments, there is less need for new programs that will only increase overall costs to the system and dilute volumes at existing providers

High quality, comprehensive care providers like St. Elizabeth provide a full continuum of care to all those who need it. The unfortunate result of removing "need" methodologies from the SHP would be to actually disrupt this continuum by introducing potentially dozens of specialized providers who focus on narrow, profitable segments of the continuum of care. This model is in direct contravention with the Cabinet's aim of building a more effective continuum of care.

"Need" Criteria Ensures Access

Safety-net hospitals like St. Elizabeth pride themselves on providing access to healthcare for all residents of their communities. The proposed changes to the SHP criteria for ASCs and Radiation Therapy will harm safety-net providers. Often when a new program enters the market, they do not accept Medicaid or uninsured patients. The responsibility for caring for these patients falls to safety-net hospitals, which further increases the burden on such hospitals to cover the costs of this care.

The CON process is a stabilizing force in the marketplace that allows safety-net facilities, like St. Elizabeth, to be able to meet the mission of providing care to all those who come to our door. Data available through the Greater Cincinnati Health Council shows that 26.3 % of the

patients who receive care at St. Elizabeth are insured by KY Medicaid or self-insured. Only 12.4% of the Kentucky patients going to Ohio for inpatient care are insured by KY Medicaid or self-insured. In addition, only 27.8% of St. Elizabeth's NKY patients are commercially insured while 54.5% of Kentucky patients going to Ohio hospitals are commercially insured. This imbalance in payor source will be exacerbated by the establishment of new ASC or Radiation Therapy programs operated by out-of-state providers in Kentucky.

For example, in the Northern Kentucky, a Cincinnati-based independent orthopedic group established an NKY office, but does not accept Medicaid. They instead refer Medicaid patients to St. Elizabeth emergency rooms or another orthopedic group, who, like St. Elizabeth, treats all patients regardless of ability to pay. Meanwhile, this same group refers its commercially-insured patients to its Cincinnati-based ASC for procedures. The proposed changes to the ASC criteria will only serve to intensify this problem. For-profit ASCs will be able to cherry-pick the patients with commercial insurance, while non-profit hospitals and their affiliated ASCs will lose surgery volumes that are necessary to fund the care provided to the uninsured and underinsured populations. In fact, a recent report issued by State Auditor Adam Edelen found that many rural hospitals are at risk of closing due to the lack of sufficient reimbursement. Eliminating or watering down the need methodology criteria for selected services will cause this to happen faster by shifting profitable business away from existing ASCs in the market, while leaving the Medicaid and uninsured behind.

Additionally, freestanding ASCs and Radiation Therapy Centers will not be subject to the Kentucky Provider Tax. A fair portion of a Kentucky hospital's revenue is paid toward provider taxes each year. For example, St. Elizabeth provides over $13 million in provider taxes each year. The gap in revenue between Kentucky non-profit hospitals and independent ASCs run by out of state hospitals or physicians will be further widened by the difference in tax treatment, which in turn will further harm the ability of non-profit hospitals to provide care regardless of a patient's ability to pay.

"Need" Criteria Ensures Efficiency

In the healthcare industry, competition does not help to control prices because hospitals do not operate in a true free market. In fact, hospitals often operate on an unfair playing field. The proposed changes to the ASC criteria would allow an out-of-state hospital to establish an ASC in Kentucky provided that the hospital met certain quality criteria. Hospitals that operate their affiliated ASCs as hospital-based departments charge the same rates for services regardless of whether the service was performed in the hospital or in the ASC. CMS allows hospitals to bill in this manner provided that the ASC facility is within thirty-five miles of its affiliated hospital. As such, out-of-state hospitals that establish ASC facilities in Kentucky will be able to charge hospital rates so long as the new ASC is within thirty-five miles of its affiliated hospital. Therefore, the changes to the ASC criteria will not serve to foster the establishment of low-cost alternatives to hospital surgery services.

Ultimately, the proposed changes to the ASC and Radiation Therapy criteria conflict with the Cabinet's principles and will result in unintended consequences. St. Elizabeth strongly supports maintaining the ASC and Radiation Therapy criteria as is written in the 2013-2015 SHP. The proposed changes are in direct conflict with the existing review criteria, as they

provide a mechanism for review for ASC and Radiation Therapy approval "nothwithstanding" the need criteria. This "notwithstanding" exemption ignores need and allows approval to programs who may be out-of-state or for-profit companies that are not necessarily committed to the community. Ideally, the quality exception language should be eliminated, but at the very least it should be limited to Kentucky hospitals. Finally, it is important to note that with regard to ASCs, existing language in the state budget requires a population-based need criteria to be used in the *review* of CON applications.

OUTPATIENT HEALTH CARE CENTER

St. Elizabeth is opposed to the Cabinet's proposal to remove Outpatient Health Care Centers from the SHP and the formal review process. We understand that the category and supporting criteria are currently specific to only one community which has already established the facility. However, we are concerned that removing this component from the SHP would allow these centers to be established anywhere in the state by anyone with only minor changes to the existing licensure regulation. The existing licensure regulation allows an outpatient health center to provide 24 hour emergency services, primary care, radiology, MRI, and ambulatory surgery – essentially a hospital without beds. The current licensure regulation restricts the center to a county with a population of 60,000. But, removal of that provision would allow these centers to be built anywhere. These centers could function as an outpatient hospital without having to comply with the extensive regulations imposed on hospitals. This model would threaten the existence of Kentucky's hospitals.

We do support the ability of existing hospital providers that are experiencing low inpatient volumes to *seamlessly* convert, without having to close completely, into an Outpatient Health Center. This would allow for the continued access to primary care, emergency services and ambulatory surgical services within the community. There are a number of federal demonstration projects for similar models being conducted by the Centers for Medicare and Medicaid Services. Additionally, there have been at least two bills introduced in Congress to offer alternative care delivery models for small and rural hospitals. We believe as we continue the transformation of the healthcare delivery model in future months and years, there may be Kentucky hospitals that could benefit from a model of this nature. Therefore, St. Elizabeth supports retaining the Outpatient Healthcare Center component in this SHP and revising it to apply to the conversion of existing acute care and critical access hospitals to a center located in the same county as the hospital.

We appreciate your consideration of our concerns and suggestions. We welcome the opportunity to discuss these recommendations further.

Sincerely,

Garren Colvin
President and Chief Executive Officer

The Medical Center

Connie D. Smith
CHIEF EXECUTIVE OFFICER

June 26, 2015

Ms. Tricia Orme
Office of Legal Services
Cabinet for Health and Family Services
275 East Main Street 5 W-B
Frankfort, KY 40601

Re: Proposed Amendments to the State Health Plan

Dear Ms. Orme:

The Medical Center ("TMC), located in Bowling Green, recognizes the efforts put forth by the the Cabinet for Health and Family Services to modernize the Certificate of Need ("CON") program. TMC appreciates the Cabinet's willingness to receive and review comments from Kentucky providers regarding the proposed amendments to the draft *2015-2017 State Health Plan* ("SHP"). As a not-for-profit hospital that serves as a regional referral center for approximately 300,000 people in south central Kentucky and provides a wide array of services, TMC can provide meaningful input regarding the proposed changes to the SHP.

TMC supports the preservation of Certificate of Need in Kentucky and appreciates proposed revisions that modernize rather than compromise the integrity of the CON program. The CON program provides stability to the Kentucky healthcare landscape. Further, the CON program is essential to preventing proliferation of unnecessary healthcare services. Specifically, TMC encourages the Cabinet to reconsider its proposed changes to ambulance services, ambulatory surgery centers ("ASC"), and radiation therapy because such changes do compromise the integrity of the program and may ultimately harm Kentucky residents.

First, TMC opposes the removal of the ambulance service criteria from the SHP. TMC has owned and operated an ambulance service in Warren County for 41 years. TMC ambulance service provides approximately 21,000 transports per year and is accredited by the Commission on Accreditation of Ambulance Services. In addition to traditional emergency ambulance runs, our ambulance service provides a variety of services in the community, including education, outreach, and disaster preparedness. The removal of ambulance services from the SHP will have a detrimental effect on our ambulance service and other ambulance services throughout the Commonwealth that are funded by non-profits and/or local governments.

Ambulance services generally experience financial losses on traditional emergency runs. However, these losses are offset by income from non-emergent runs, such as transports to and from nursing homes. If ambulance services are removed from the SHP, then for-profit providers will be able to enter the market and cherry pick the most lucrative transports. Subsidized ambulance services will suffer because they will lose the income necessary to offset losses from emergent runs. During the most recent fiscal year, TMC subsidized the ambulance service in the amount of $1.5 million. Other Kentucky ambulance services rely on funding from local governments. TMC will likely be unable to continue subsidizing its ambulance service if it loses revenue from non-emergent runs. And, local governments will be forced to raise taxes in order to fund their ambulance services.

Second, TMC also opposes the proposed changes to the SHP criteria for ASCs. The CON process for ASCs protects the surgical volumes at Kentucky hospitals, which are necessary to financially support the hospitals' other services, including emergency services and care to patients regardless of the ability to pay. ASCs, unlike hospitals, are not required to provide emergency services or treat patients regardless of ability to pay, and, as such, they can provide only those services that produce the best revenues. The proliferation of ASC providers would siphon surgical patients away from Kentucky hospitals, which will ultimately harm the patients that rely on Kentucky hospitals for emergency and other care.

Third, the Cabinet should carefully consider the changes it makes to the criteria for radiation therapy services in order to prevent the over utilization and unnecessary expansion of such services. States that have deregulated their CON programs have experienced exponential growth in radiation therapy programs. As such, TMC suggests re-examining the change to the SHP that would allow certain accredited hospitals to establish radiation therapy programs. TMC suggests imposing certain geographic or licensure restrictions, including limiting the provision to Kentucky hospitals as a means of preventing rapid and unnecessary establishment of such programs.

Thank you in advance for your time and consideration of TMC's comments. Please do not hesitate to contact me if you wish to discuss these comments further.

Sincerely,

Wade R. Stone
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